

Section 5**510 (k) Summary of Safety and Effectiveness**

Date Prepared: April 16, 2006

Name of Contact Person: Norm Morikawa

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Communications & Medical Products Division
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Device Trade Name: **CPIVISION DIGITAL IMAGING SYSTEM**

Common Name: Digital Radiography

Classification Name: Image Intensified Fluoroscopic X-ray System

Device Description:

The CPIVision Digital Imaging system allows the use of digital imaging to be applied to conventional X-ray system used in general fluoroscopy, interventional fluoroscopy, angiography and cardiac imaging areas. The system works by installing a CCD camera/lens on the output port of the image intensifier and digitizing the video output on the image intensifier. The digital image can be displayed on the monitor; it can be stored to the hard drive, or sent to an external device such as a laser imager or Network Storage Provider. The image can also be computer processed, including brightness and contrast, edge enhancement, zoom, and subtraction.

Intended Use:

The CPIVision Digital Imaging system is a high resolution, digital imaging system designed for digital videography. It is intended to replace conventional film techniques in multipurpose or dedicated applications when general fluoroscopy, interventional fluoroscopy or angiography or cardiac imaging procedures are performed.

The CPIVision Digital Imaging allows the operator to view and enhance digital fluoroscopic images. High resolution digital spot images may be acquired at single or rapid acquisition rates. Images may be viewed and enhanced enabling the operator to bring out diagnostic details difficult or impossible to see using conventional imaging techniques.

The CPIVision Digital Imaging enables the operator to hardcopy image with a laser printer or send images over a network. The major system components are: a fluoroscopic CCD camera/lens, monitors, and an image processor.

Conclusion drawn from comparison:

The CPIVision Digital Imaging can be considered to be substantially equivalent to:

INFIMED INC.

ORION FLUOROSCOPIC IMAGING SYSTEM 510 (k) – K012490



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Norm Morikawa
QA Manager/ Regulatory Affairs
CPI (Communications & Power Industries) Canada, Inc.
Communications & Medical Products
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Ontario, L7G 2J4
CANADA

JUN - 9 2006

Re: K061173
Trade/Device Name: CPIVision Digital Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: April 17, 2006
Received: April 27, 2006

Dear Mr. Morikawa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use

510(k) Number: ~~Not known at this time~~ K061173

Device Name: **CPIVision Digital Imaging System**

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The CPIVision Digital Imaging system allows the operator to view and enhance digital fluoroscopic images. High resolution digital spot images may be acquired at single or rapid acquisition rates. Images may be viewed and enhanced enabling the operator to bring out diagnostic details difficult or impossible to see using conventional imaging techniques.

The CPIVision Digital Imaging system enables the operator to hardcopy image with a laser printer or send images over a network. The major system includes: a fluoroscopic CCD camera/lens, monitors, and an image processor.

Prescription Device ✓

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K061173